

## **REMARKS/ARGUMENTS**

Claims 1-9 and 11-20 are present in the application.

Claims 1 and 2 are canceled. Claims 3, 4 and 11 are amended.

Claim 3 has simply been rewritten as an independent claim, with the features of Claim 1 written there into.

Claims 4 and 11 are amended to change dependency.

Applicants respectfully request entry of the amendments, if only to place the claims into better condition for an appeal.

### **Rejection of claims under 35 USC 102(b)**

Claims 1-3 and 11 are rejected as anticipated by Mattson et al (US 3,600,186).

Without acquiescing whatsoever to the basis or rationale of the rejection in any way, the rejection of Claims 1 and 2 is rendered moot by the cancelation of these claims.

Applicants traverse and request withdrawal of the rejection against claims 3 and 11.

Claim 3 requires a predetermined amount of sucrose polyester comprising sucrose behenate.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). The reference also must show the identical invention in as complete detail as is contained in the claim. (*Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)

Unless Mattson et al expressly describe a compound as “sucrose behenate”, or describes a compound that is inherently sucrose behenate, Claim 1 cannot be anticipated by Mattson et al. The Examiner has concluded erroneously that Mattson et al disclose expressly or inherently sucrose behenate. Indeed, Mattson et al disclose that the seventeen different monosaccharides or disaccharides that bear at least 4 hydroxyl groups; the saccharides can be esterified with at least 4 and up to 8 fatty acids; there are fifteen possible carbon chain lengths for the fatty acids, and sixteen specific fatty acids; the fatty acids can be saturated or unsaturated. There may be potentially thousands of possible combinations of saccharides, fatty acids, and degrees of esterification. However, in order to anticipate, more is needed than for the reference to describe the claimed compound in a generic formulation or by possibilities; the reference must name the compound expressly, or inherently. Mattson et al do not. A mere possibility that the claimed compound might be one of a thousand possible compounds represented by a generic chemical formula shown in Mattson et al reference is not inherency. Furthermore, the only test composition described by Mattson et al contained only oleic (C<sub>18</sub>) fatty acid esters; behenic esters are not disclosed. Consequently, Claims 3 and 11 are not neither anticipated by, nor obvious in view, Mattson et al.

Furthermore, the claimed composition includes 5 to 60% dietary fat, and further including 1 to 25% protein, and 5 to 60% carbohydrate, by weight. The composition of experimental diet fed to the rats shown in Table I contains more than 25% protein (casein at 27%), and therefore does not anticipate the composition of Claim 3 on this basis as well.

Claims 1, 2 and 11 are rejected as anticipated by Young (US 5,085,884).

The rejections of Claims 1 and 2 are rendered moot by the cancelation of these claims.

Applicants request reconsideration and withdrawal of the rejection against Claim 11, which is now obviated by its amendment to depend from Claim 3, which is not anticipated by Young.

#### **Rejection of claims under 35 USC 103(a)**

Claims 5-8 and 13-18 are rejected as obvious over Mattson et al (US 3,600,186).

Applicants traverse and request withdrawal of the rejection against claims 5-8 and 13-18.

The Examiner concludes that a person of ordinary skill would find it obvious to use the fat balance experiment taught by Mattson et al for diagnosing malabsorption of dietary fat by the digestive tract of a subject, and impairment of the dietary fat digestion. The Examiner's rationale is that "any absorption results deviating from the normal, expected results would inherently and obviously serve as an indication or diagnosis of malabsorption".

At the outset, Applicants do not understand what "any absorption results" or "normal, expected results" the Examiner is referring to in the Action. The Examiner appears to have some modification of the Mattson et al experiment in mind, but exactly what is not clear to Applicants. A more thorough explanation of what the Examiner has in mind is necessary in order to have an understandable rejection.

In addition, the Examiner's statement of the teaching of Mattson et al at page 3 line 11, that "a sample of fecal matter is collected", is factually incorrect. The test methodology of Mattson et al requires that the entire quantity of the feces over a ten day period is collected, weighed and analyzed for total fatty acid esters. The "whole amount" is not a "sample". This is the entire problem with conventional methodology of measuring fat malabsorption that the present invention avoids. Mattson et al's testing would fail if only a sample portion of the feces were collected and analyzed. Clearly then, Mattson et al do not obtain "a sample" of the feces collected, as provided by the claims, and there is entirely no teaching, suggestion or motivation disclosed in Mattson et al, and a person of ordinary skill would not consider it obvious in view of Mattson et al, to select only a sample portion of the feces, to avoid collecting of the total of the feces.

In addition, despite the Examiner's unexplained conclusion otherwise, Mattson et al do not separately measure the amount of the dietary fat and the amount of the sucrose polyester in the sample. Mattson et al measure the total fatty acid content of the collected feces, and does a total mass balance against the calculated amount of fatty acids in the diet composition that was consumed. Mattson et al's measurement can not distinguish the fatty acids from triolein and from the sucrose polyester. The Examiner states at the top of page 8 of the Action that Mattson et al "do separately measure the absorption of the dietary fat (triolein) and the test materials containing a sucrose alcohol fatty acid ester compound by using the formula depicted on lines 1-3 of column 6". With all due respect, the Examiner's allegation of measuring "the absorption of

dietary fat” is not correct. The Examiner will please note the observed coefficient of 96% from the mass balance of total fatty acids for “triolein only” in row 1 of Table II, and that the formula includes the factor “x 96 %”. It was not “a measuring” at all, but a back-calculation based on an assumption that the sucrose polyester did not interfere with triolein’s absorption.

Moreover, Mattson et al rely upon a significant assumption in determining the “observed coefficients of absorbability” of the test material: they assume that “the presence of esters of other alcohols, i.e., the test materials, does not alter the absorption of triolein”. Mattson et al obtained an observed level of absorption of triolein, using triolein as the test material, which is reported in the top row of Table II, and then merely assumes that all triolein in a test composition is absorbed at the same coefficient. It is also noted that the test in Mattson et al. is being performed to determine the absorption of the sucrose oleates. In stark contrast, the sucrose behenate is known to be non-absorbable on the filing date of the present invention. Consequently, a person of ordinary skill, at the time of the present invention, would have had no reason or motivation to prepare a test composition containing sucrose behenate or to conduct the test with sucrose behenate, as described in and in view of Mattson et al.

In conclusion, Claims 5-8 and 13-18 are not obvious in view of Mattson et al.

Claims 4, 9, 12 and 19-20 are rejected as obvious over a combination of Mattson et al and Janghorbani (US 6,006,754).

Janghorbani teaches a colorant added to a composition for measurement of fat absorption. The colorant is used to identify fecal matter produced by the consumed composition. The composition includes labeled dietary fat and a non-absorbable, non-fat marker. The amounts of any labeled dietary fat and the non-fat marker are measured to identify the amount of dietary fat absorbed.

Even, for the sake of argument, a colorant was added to the diet provided in Mattson et al, the methodology described in Mattson et al would not have changed; all of the feces would have been collected and measured, and only the total fatty acids would have been measured.

In view of the arguments presented herein, dependent 4, 9, 12 and 19-20 are likewise non-obvious and patentable.

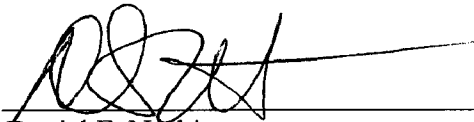
## **CONCLUSION**

The claims have been amended to cancel Claims 1 and 2. Independent Claim 3 was only rejected as anticipated over Mattson et al, and such rejection has been convincingly traversed. Independent Claim 5 was only rejected as obvious in view of Mattson et al, and such rejection has also been convincingly traversed.

Applicants believe that a complete response to the final rejection has been made, which includes claim amendments to clearly distinguish the claims over the prior art of record, and places the application into condition for allowance, or at least into better condition for an appeal of the rejection.

Respectfully submitted,

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